

### **REMARKS/ARGUMENTS**

Claims 1-3 and 6-11 remain pending in the instant application. Favorable reconsideration is kindly requested.

### **Petition to Withdraw Finality**

The Office Action Summary (p. 1) indicates that the April 25, 2008 Office Action is Final. Applicant believes this to be in error as the text of the Office Action does not indicate that the Office Action is Final (e.g., Conclusion, p.4). In the event that the Office Action is considered Final, Applicant kindly requests that the finality be withdrawn as premature.

The most recent Office Action is the first Office Action following Applicant's April 1, 2008 Request for Continued Examination under 37 C.F.R. § 1.114. The M.P.E.P. states "[I]t would not be proper to make final a first Office Action in a continuing or substitute application where that application contains material which was presented in the earlier application after final rejection or closing of prosecution, but was denied entry because (A) new issues were raised that required further consideration and/or search, or (B) the issue of new matter was raised." MPEP §706.07(b). In the present case, after the final rejection mailed October 3, 2007, Applicant filed an RCE with amendment preemptively, before an Advisory Action would have issued. Notwithstanding, the Examiner's remarks (April 25, 2008 Office Action, p. 4) addressing the April 1, 2008 amendments indicate the new issues raised therein. Therefore, to the extent the indication of finality was not inadvertent, Applicant respectfully submits that the finality of the most recent Office Action was premature and kindly requests that it be withdrawn.

### **Amendments to the Claims**

As amended above, the subject matter of claim 4, previously dependent upon claim 1, and of claim 5, previously dependent upon claim 4, are incorporated into independent claim 1. Claims 4 and 5 are cancelled. Independent claim 11 is also amended to include the subject matter recited in claims 4 and 5. Claims 6 and 7, previously dependent upon claim 5, are amended to depend from claim 1.

No new matter has been added by this amendment.

**Rejection under 35 U.S.C. § 103**

Claims 1-11 stand rejected under 35 USC § 103(a) as obvious over U.S. Patent No. 5,254,097 to Schock, *et al.* ("Schock"), taken alone. Applicant respectfully traverses the rejection.

Claim 1 as amended recites

A device for injection, comprising a body (1) provided with a first channel (2) for conveyance of a first medical substance and a first connecting component (3) having a first port (4) for introduction of a first medical substance into said first channel (2), said connecting component (3) being connectable to an external unit, and a second channel (5) for conveyance of a second medical substance and a second connecting component (6) having a second port (7), that is sealed by a first flexible air- and liquid-proof membrane (17), which can be opened by means of an injection component for injecting a second medical substance into said second channel (5), said first flexible air- and liquid-proof membrane (17) cooperates with a second flexible membrane arranged in an injection component (11) which is connectable to said second connecting component (6), and the device has a means (18) for holding said second flexible membrane with a pressure against said first flexible air- and liquid-proof membrane (17), and provided with a third connecting component (8) being common to the first and the second channels (2,5) and having at least one third port (9) for conveying medical substances out from said first and second channels, characterized in that said first (3), second (6) and third (8) connecting components and the body (1) are designed as an integrated unit, and said third connecting component (8) is a first luer fitting component provided with a thread (19) for releasable connection with a second luer fitting component having a corresponding thread, for creating a luer fitting coupling, wherein the first channel (2) extends in a generally straight line through the body (1) of the device.

(underline per 37 CFR § 1.121)

The Office Action avers that these features are taught by Schock. Applicant respectfully disagrees.

The Office Action cites Schock reference 34 as an injection component having a second flexible membrane, and that reference 36 provides means for holding the second flexible membrane with a pressure against the first membrane. According to the Schock specification, 34 is a threaded hub, and 36 is a radial barbed fitting for forming a secure seal between the threaded hub (34) and a leg (16) of the Y-shaped body (10). (Col. 5, lines 1-4).

The combination of features recited in claim 1 enables the safe transfer of a substance from the injection component (11) into the device since contamination of the fluids inside the device and leakage of medical substances from the device into the ambient air is prevented by pressing said first and second flexible membranes together, penetrating the membranes with a needle and injecting a substance through the membranes via the needle and withdrawing the needle through the membranes.

The device disclosed by Schock discloses an injection channel (42) including a slit portion 46. Such a device could not be used to solve the problem of having high degree of imperviousness against leakage when supplying medical substances into the device using an injection component having a flexible membrane, since applying a pressure to the slit portion 46 would cause it to open and the contents of the device could therefore leak out of the device. Moreover, the arrangement set forth in the reference does not hold the second membrane with a pressure against the first membrane. The contrast is most stark in comparing Figs. 2, 4 of Schock with exemplary embodiments in Figs. 2a, 3 of Applicant's disclosure. Not only would the pressure described inhibit the sealing capability of the slit (46) in Schock, but the only structure that could be conceivably considered a membrane in Schock's threaded hub 34 is diaphragm 60 (Col. 8, lines 27-31). The diaphragm, however, is not pressed against the first "membrane". Therefore, the Schock reference does not disclose the features recited in independent claim 1.

The foregoing remarks will be seen as equally applicable to distinguish claim 11, which includes amended language to the same effect as claim 1. Claims 2-3 and 6-10 each depend, either directly or indirectly, from independent claim 1. These claims are each separately patentable, but in the interest of brevity they are offered as patentable for at least the same reasons as their underlying independent base claim, the features of which are incorporated by reference.

However, specifically with reference to claim 3, this dependent claim recites

A device according to claim 1, wherein said third connecting component (8a) has a fourth port (23), wherein said third port (9a) constitutes an outlet for the first channel (2a) and said fourth port (23) constitutes an outlet for the second channel (5a).

The Office Action cites structure 46 of Schock as reading on second port (Office Action, p. 2), and a fourth port (*Id.*, p. 3). Presuming without conceding that the slit (46) of Schock is a port as


recited in the claims, a single structure of the reference cannot anticipate multiple structures recited in the claim. See, *Lantech, Inc. v. Keip Machine Co.*, 32 F.3d 542, 31 U.S.P.Q. 2d 1666 (Fed. Cir. 1994) (District Court erred where it applied a single element of the accused device to read on multiple elements recited in the claim). Therefore, Applicant respectfully submits that claim 3 is further distinguished over the applied reference.

### **Conclusion**

In light of the Foregoing, Applicant respectfully submits that the claims are patentable over the cited references, and kindly solicits an early and favorable Notice of Allowability.

THIS CORRESPONDENCE IS BEING  
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Respectfully submitted,



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